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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/902,692	07/30/97	REA W	16715CIP

HM12/0929

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EXAMINER	
SCHWADRON,R	
ART UNIT	**PAPER NUMBER**
1644	20

DATE MAILED: 09/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/902,692	Applic...(s) Rea et al.
	Examiner Ron Schwadron, Ph.D.	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *8-19, 21, 32, and 40-66* is/are pending in the application.

Of the above, claim(s) *8-19, 21, 32, and 40-48* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *49-66* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The request filed on 9/11/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08902692 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 49-66 are under consideration. Claims 65,66 are newly added.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 49-64 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the method of claim 49 or 60 which does not recite the use of "normal" lymphocytes. There is no disclosure in the specification as originally filed of the scope of such an invention (eg. it constitutes new matter). Regarding the procedure disclosed in pages 8-10 of the specification, the last paragraph of page 8 indicates that it is practiced with "normal" lymphocytes. Regarding the specification, page 15, lines 14-18, said passage refers to treatment with ALF wherein ALF is prepared from "normal lymphocytes" as per the procedure disclosed in pages 8-10 of the specification.

Regarding applicants comments, the last paragraph, page 8 of the specification discloses that the method described in pages 9-10 of the specification is practiced with "normal lymphocytes". The aforementioned paragraph does not state that the normal cells are the harvested propagated cells. It does state "growing the normal lymphocytes in culture". Regarding applicants comments about the in vitro culture of "normal" or "robust" lymphocytes versus "unhealthy" cells, said comments are not supported by the specification or any evidence of record

5. Claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action.

There is no support in the specification as originally filed for the method of claim 65 which recites "which includes at least some normal T and B lymphocytes". There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

6. Claims 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 is indefinite in the recitation of "normal T and B lymphocytes" because it is unclear what this term means or encompasses. It is unclear as to what parameters distinguish a normal lymphocyte from an abnormal lymphocyte. The meaning of said term is not disclosed in the specification and it has no art recognized meaning.

7 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. in view of Warren (US Patent 4,435,384) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor (see entire document). The transfer factor is prepared from lysed leukocytes (see page 56, first column). It appears that these "environmentally sensitive patients" would be encompassed by the term "chemically sensitive individual". Youdim et al. do not teach that the transfer factor was produced from autologous blood cells as per claim the claimed invention. Warren teaches that

transfer factor can be obtained from the lymphocytes of any individual as long the donor has no history of recurrent infection by herpes virus (see column 2). Therefore a routineer would have used any source of lymphocytes, including autologous, for preparing transfer factor for use in the method taught by Youdim et al. Youdim et al. do not teach that the transfer factor was produced using the particular steps recited in the claimed method. Warren teaches that transfer factor can be produced by a variety of different methods and lists one particular method (see columns 2 and 3). The steps recited in the claimed method are art known procedures that would be expected to yield a lysate containing transfer factor. Regarding the use of "mixed T and B lymphocytes", Warren teaches that transfer factor is produced from lymphocytes (see column 2). The cells used in the method taught by Warren are propagated in that they are cultured in vitro. The use of commercially available density gradients such as FICOLL to separate lymphocytes is well known in the art. Warren teaches the use of heparinized tubes to collect the blood sample. Warren teaches 37 degree incubation of lymphocytes (see column 2). Youdim et al. teaches subcutaneous administration of transfer factor (see page 56, column 2). Youdim et al. teaches multiple administration of transfer factor (see page 56, column 2). Youdim et al. teaches that skin testing (eg. DTH) can be used to measure the response to transfer factor. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor, Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long as the donor has no history of recurrent infection by herpes virus, and the preparation recited in the claims appears to be transfer factor made by a method that uses art known techniques that would have been obvious to use to prepare transfer factor.

Regarding applicants comments, Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long the donor has no history of recurrent infection by herpes virus (see column 2). Therefore a routineer would have used any source of lymphocytes, including autologous, for preparing transfer factor for use in the method taught by Youdim et al. Regarding applicants comments about adverse effects from nonautologous transfer factor, there is no evidence of record that such adverse effects occur. Furthermore, the method taught by Warren encompasses use of autologous transfer factor (eg. the transfer factor can be obtained from the lymphocytes of any individual as long the donor has no history of recurrent infection by herpes virus).

Regarding applicants comments about culture and propagation, there is currently no limitation in the claims under consideration that states that the cells are cultured for any defined period of time. Regarding the term "propagation", said term in itself does not specify any particular time period of in vitro culture. Regarding the limitation of claims 66 and 62, the starting concentration of cells used in the claimed method is not specified. Thus, if the cells were initially at the concentration specified in claim 66 or 62, then they would not require any particular time period to achieve the concentration recited in claim 62 or 66. Said limitation would only take on meaning if the initial concentration of cells was specified and if the concentration was such that it would take a particular time period of culture to achieve the concentration recited in claims 66 or 62. Applicants arguments involve limitations currently not recited in the claims under consideration.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644